

INSTRUCTIONS FOR USE



MEDICAL GAS FLOWMETER PEDIATRIC & NEONATAL



Rx Only

FM – SS(S)TU – VV(WW) – (X)

FM	SS(S)	T	U	VV	(WW)	(X)
	Flowrate	Color Code	Gas	Inlet Connection	Options	Special Options






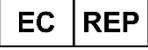

Basic matrix shown. Consult the Ohio Medical® website for full matrix or contact your Ohio Medical representative. The product package label contains your product identifier and description.

IMPORTANT: SAFETY INSTRUCTIONS

This manual provides you with important information about the Flowmeter and should be read carefully to ensure the safe and proper use of this product.

Read and understand all the safety and operating instructions contained in this booklet before using this product.

If you do not understand these instructions, or have any questions, contact your supervisor, dealer, or the manufacturer before attempting to use the apparatus.

WARNING:	Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury		
ATTENTION:	Indicates a potentially hazardous situation, which if not avoided, could result in minor or moderate injury		
CAUTION:	Indicates a potentially hazardous situation, which if not avoided, could result in damage to the device or other property		
	Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices (on CE marked devices only)		
	Caution: Consult operating manual		Manufacturer
	Use no oil		Serial Number
	Manufacturer's authorized representative in the European Union		
	Catalog Number (Device Identifier). This identifier includes alpha-numeric characters that correspond to the vacuum regulator model, gauge type, color and any fittings ordered. It is located on the outer package label of your unit.		
Rx Only	Caution: Federal (USA) Law restricts this device to sale by or on the order of a licensed healthcare provider.		

RECEIVING INSPECTION

Remove product from package and inspect for damage. Verify that the model received is in working order. If product is damaged or incorrect, do not use. Contact your dealer, equipment provider or manufacturer.

ATTENTION: It is very important to allow product to remain in original packaging for 24 hours to acclimatize to room temperature before use.

ATTENTION: Store the product in a sealed package to avoid environmental damage. The operating and storage temperature for the Flowmeter should reflect typical environmental conditions of a medical facility environment.

USER RESPONSIBILITY

WARNING: Service of this device should only be performed by properly trained individuals. The Amvex Flowmeter is used to dispense an adjustable flow of gas accurately under the direction of a healthcare professional.

This product performs as explained in this manual. This holds true as long as the assembly, use, repair and maintenance are properly followed according to our instructions. Periodic review of this device is recommended. If any damage or defects are present, the product should not be used. This includes parts that are worn or missing. If any of the above are noted, immediate repair/replacement is required. If this device is subject to improper maintenance, repair, use and / or abuse leading to malfunction of the device, replacement is the sole responsibility of the user.

WARNING: Operation of this device is not to be done if flammable anesthetics are present due to the possibility of explosion caused by static charge.

TO MINIMIZE THE RISK OF EXPLOSION OR FIRE:

- NEVER attempt to attach a Flowmeter directly to a cylinder.
- NEVER use grease, oil, organic lubricants or flammable materials on or near the Flowmeter.
- NEVER smoke in an area where oxygen is being used.
- NEVER use any type of flame or flammable or explosive material near the Flowmeter.
- ALWAYS follow CGA and ANSI standards for Flowmeters and Medical Gas Products (E-7) and Oxygen Handling (G-4).

ATTENTION: Keep the Flowmeter in a clean area when not being used. Ensure that all connections are tightened and free of leaks prior to use. Only use an oxygen-safe leak detector when testing for leaks.

WARNING: Each Flowmeter is for use with only one type of gas.

INTENDED USE

A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

SPECIFICATIONS

Model	Scale	Increments	Accuracy	Max.Flood/Flush	Transport/ Storage Requirements
FM-200	0-200 cc/min	25 cc/min (starts at 25 cc/min)	+/- 20 cc/min	500 cc/min	-40°F to 140°F (-40°C to 60°C)
FM-01	0-1 L/min	0.1 L/min (starts at 0.1 L/min)	+/- 0.1 L/min	2.5 L/min	-40°F to 140°F (-40°C to 60°C)
FM-03	0-3.5 L/min	0.125 L/min from 0.125 to 1 L/min	+/- 0.125 L/min or +/- 10% of reading (whichever is greater)	45 L/min	-40°F to 140°F (-40°C to 60°C)
		0.25 L/min from 1 to 3.5 L/min			

Flowmeters are calibrated at the pressure indicated on the Flow Tube, 70° F (21° C), at standard atmospheric pressure. Specifications are subject to change without prior notice.

MRI WARNING: This product may contain magnetic, ferrous material that may affect the result of an MRI. For MR Conditional options, contact your Ohio Medical Representative at 1.866.549.6446.

WARNING: Block flow splitters configured with Flowmeters require a supply line that can maintain prescribed pressure with flow capacity greater than the sum of the flood value of all Flowmeters (e.g. a block configuration with three 15 L/min Flowmeters requires a supply of 150 L/min minimum flow capacity which is maintained at 50 PSI). If power takeoffs are configured, ensure supply line can provide for load. The minimum required flow rate from the power takeoff is dependent on the equipment connected to the power takeoff.

OPERATING INSTRUCTIONS

1. Turn Flowmeter off by turning knob fully clockwise.
2. Inspect the Flowmeter for damage. If any is found, do not use the Flowmeter.

CAUTION: Over tightening the knob when turning the Flowmeter off will cause damage. The Flowmeter must be used with the Flow Tube in an upright position.

WARNING: The Flow Tube specifies the gas and pressure required.

3. Connect the Flowmeter to the supply pressure and gas specified on the Flow Tube.

WARNING: The accuracy may be affected if the temperature of the gas is different than 70° F (21° C) and the supply pressure is different than that indicated on the Flow Tube.

NOTE: The accuracy of the flow will not be affected by the attachment of accessories, however, the indicated flow may change.

WARNING: Connection to the gas source must be done by using only the appropriately indexed fitting.

4. Ensure that the Float Ball is at the very bottom of the Flow Tube when turned off.

NOTE: If the Float Ball is not at the bottom of the Flow Tube, the Flowmeter could be leaking. Please contact your dealer or Ohio Medical.

5. Adjusting the Flow: **To DECREASE Flow:** Turn the knob clockwise **To INCREASE Flow:** Turn the knob counter clockwise

6. To set the flow, align the center of the float ball to the indicator line on the Flow Tube.

WARNING: To avoid injury ALWAYS confirm flow requirement for patient prior to dispensing. Check flow frequently while being administered to patient.

7. An undetermined flow will arise if flow is adjusted beyond the last calibrated indicator.
8. Turn knob completely counterclockwise to achieve maximum flood/ flush flow.

NOTE: Any flow beyond the last calibrated line on the Flow Tube with unrestricted flow is Flood/Flush flow.

CLEANING INSTRUCTIONS

Use a clean damp cloth with a mild cleaning solution to wipe outside of product. Do NOT gas sterilize with ETO. DO NOT clean with pungent hydrocarbons.

CAUTION: DO NOT submerge Flowmeter in any form of liquid. This will cause damage and void any warranty on the product.

TROUBLESHOOTING

Contact your dealer or the technical support department at Ohio Medical for assistance if the Flowmeter does not function properly.

MAINTENANCE PREVENTION

Inspect the product before and after use for any damage and ease of operation.

WARNING: When changing connectors on the Flowmeter for service or replacement, never re-attach connectors of a different gas. Doing so may result in patient injury or damage to the equipment.

CAUTION: Disconnect Flowmeter from gas supply BEFORE SERVICING.

WARRANTY

The Amvex Flowmeter here known as "Product" is sold by Ohio Medical LLC ("Company") under the express terms of the warranty set forth below. For a period of SIXTY (60) MONTHS [with the exception of the 0-200 cc/min and 0-1 L/min and 70 L/min Flowmeter for TWELVE (12) MONTHS] from the date the Company ships, this Product is warranted to be free from functional defects in materials and workmanship and to conform in all material respects to the description for the Product contained in this operation manual, if this Product is properly operated under conditions of normal use, regular periodic maintenance and service is performed and repairs are made in accordance with this operation manual. The Company's sole and exclusive obligation and customer's sole and exclusive remedy under the above warranty is limited to repair or replacement, at the Company's option, of the defective Product. The foregoing warranty shall not apply if the Product has been repaired or altered by anyone other than the Company or an authorized dealer; or if the Product has been subjected to abuse, misuse, negligence, or accident. The Company reserves the right to stop manufacturing any product or change materials, designs, or specifications without notice. This warranty is extended to only the initial customer with respect to the purchase of this Product directly from the Company or an authorized dealer as new merchandise. Dealers are not authorized to alter or amend the warranty of any Product described in this agreement. Any statements, whether written or oral, will not be honored or be made part of the agreement of sale. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE COMPANY SHALL NOT BE LIABLE FOR INCIDENTAL, COLLATERAL, CONSEQUENTIAL, OR SPECIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, OR LOSS OF USE. THE COMPANY'S LIABILITY, IN THE AGGREGATE, SHALL NOT EXCEED THE PURCHASE PRICE OF THE PRODUCT. In order to file a warranty claim, customer is required to return Product prepaid to the Company at 1111 Lakeside Drive, Gurnee, IL 60031 USA. As determined at the sole discretion of the Company, Products which qualify under the warranty will be repaired or replaced, at the Company's option, and returned to customer via ground delivery at the Company's expense. All claims for warranty must first be approved by the Company's Customer Service Department: (customerservice@ohiomedical.com or 866.549.6446). Upon approval the customer service department will issue an RMA number. An RMA must be obtained prior to commencement of any warranty claim.

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